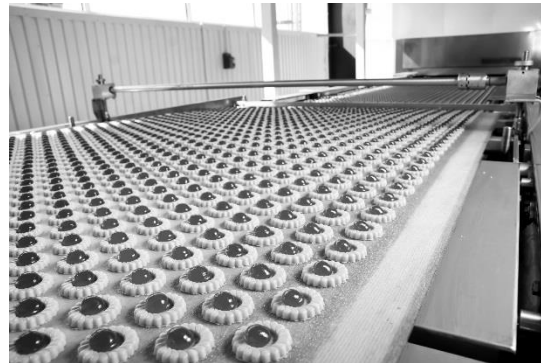




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IFPTI Fellowship Cohort VI: Research Presentation

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Use of Critical Control Points(CCPs) In Florida Seafood HACCP Plans

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Services(FDACS)

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- For nearly 20 years in Florida, 21 CFR Part 123 for Fish and Fishery Products has been in place
- By rule, seafood processors shall conduct a Hazard Analysis
- The Hazard Analysis may reveal the requirement for a written Hazard Analysis Critical Control Point(HACCP) plan:
 - HACCP plans are required to be specific to:
 - Each physical processing location
 - Each kind of fish and/or specific fishery product

- Written HACCP plans identify Critical Control Point(s) (CCPs)
- CCPs are designed to control potential food safety hazards that are:
 - Significant
 - Probable
 - Reasonably foreseeable or likely to occur
- Intentions of CCPs to focus food safety resources where preventive controls are needed

Over the past 20 years, seafood processors began to subsume negligible elements into HACCP plans

- Anecdotal evidence suggests use beyond required CCPs—those required by Code of Federal Regulations (CFR)
- Some plans include negligible elements as CCPs that are best monitored under Standard Operating Procedures (SOPs)

FDACS responded by performing a descriptive study to address the following possible

- Misalignment of food safety resources (regulatory and industry)
- Over-focused efforts detracting from required significant CCPs

The extent to which negligible elements are incorporated as Critical Control Points (CCPs) in Florida Seafood HACCP plans is unknown.

1. What is the distribution of required CCPs and negligible elements in seafood establishment HACCP plans?
2. What is the percentage of negligible elements incorporated into seafood HACCP plans?
3. What percentage of seafood establishments incorporate negligible elements as CCPs that could be monitored as SSOPs?
4. Is there any correlation between the inclusion of negligible elements in seafood HACCP plans and the food establishment's size?

- Identify seafood HACCP plans examined by FDACS inspectors from 2014 to 2016
- Categorize each element within each seafood HACCP plans as:

Food hazard that is significant, probable, and reasonably foreseeable or likely considering the specific product and process

Negligible element for food safety (not required as a CCP by 21 CFR Part 123)

- Evaluated all elements included as CCPs using:
 - Fish and Fishery Products Hazards and Controls Guidance
 - Inspector flow chart and Inspector hazard analysis
 - Supporting inspection documents
 - 21 CFR Part 123

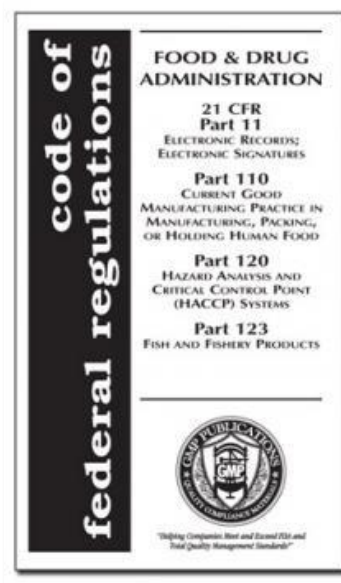


Image source: GMP Publications



Image source: FDA.gov

- All Seafood HACCP plans obtained at time of FDACS inspections were conducted under FDA contract
- Inspections time span: October 1, 2014, through September 30, 2016
- 158 Seafood HACCP plans evaluated

158 seafood HACCP plans evaluated

Comprised of 440 CCPs

335 (76%) of the 440 CCPs verified to be:

Significant

Probable

Reasonably
foreseeable or likely
to occur

Comprised of 440 CCPs

105 (24%) of the 440 CCPs were determined to be negligible elements (not required as a CCP by 21 CFR Part 123)

Spanned over 63 (39%)
of the 158 HACCP plans
reviewed

Ranged from being 13%
to 100% of the CCPs
within the respective
HACCP plan

-
- Substantial number of negligible elements subsumed as CCPs into the HACCP plans reviewed
 - Further research is required to determine if the 105 negligible elements as CCPs could be best controlled by other means
 - There does not appear to be a correlation of food establishment size and the inclusion of negligible elements as CCPs into HACCP plans

1. Studies in other large seafood states identifying negligible elements as CCPs included in HACCP plans.
2. Future research should examine how negligible elements in Seafood HACCP plans might be better controlled by other means.
3. Examine what extent the inclusion of negligible elements biases inspection reports based on Seafood HACCP plans and estimate the potential costs for both industry and regulatory resources.

4. Further assess existing Seafood HACCP training methods. Conduct focused outreach initiatives and develop methods and initiatives that might address the issues identified in this study.
5. Research to identify whether the problem of negligible elements in Seafood HACCP might well be a problem in the future with Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food and food safety plans.

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Questions?

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- [Potential Contributing Influences](#)
- [Potential Detractions from HACCP](#)
- [Potential Detractions from HACCP \(continued\)](#)